Investigating Human Factors in Biotechnology and Pharmaceutical Manufacturing industries

Koumaditis Konstantinos, University of Piraeus, Department of Digital Systems, Greece
konkoum@unipi.gr

Themistocleous Marinos, University of Piraeus, Department of Digital Systems, Greece
mthemist@unipi.gr

Philip Byrne, Pfizer Ireland Pharmaceuticals, EHS Training Manager, Ireland,
philipw.byrne@pfizer.com

Derek Ross, Trinity College Dublin, Department of Psychology, Ireland,
rossde@tcd.ie

Samuel Cromie, Trinity College Dublin, Department of Psychology, Ireland,
sdcromie@tcd.ie

Siobhan Corrigan, Trinity College Dublin, Department of Psychology, Ireland,
scorrig@tcd.ie

Abstract

The aim of this paper is to present the work carried out in a European Commission-funded project to adapt an existing Aircraft Maintenance Human Factors (HF) training program (STAMINA) to the Biotechnology and Pharmaceutical Manufacturing industries (BPM). The STAMINA approach has been successfully built into a global human factors training business recognized internationally as a quality benchmark. The Biotechnology and Pharmaceutical Industries have a similar need for human factors training, but with a less elaborated research and regulatory framework. The goal of the project is to provide training to increase and support operational safety, product quality and process reliability within the BPM industry. This paper presents the findings from the first two stages of the project: (a) literature review and (b) research findings.

Keywords: Human Factors, Pharmaceutical and Biotechnology manufacturing,

1 INTRODUCTION

The pharmaceutical industry has been described as dynamic and growing, in terms of sales, number of employees, and Gross Domestic Product (GDP). Drug development is an expensive, lengthy and risky process (Festel, Schicker et al. 2010). The pharmaceutical industry consists of all enterprises that are involved in the invention of drugs, production of the active substances in drugs, formulation of the drugs, and promotion of them in the public, as well as the specialist who prescribed them (Swayne, Duncan et al. 2007).

The pharmaceutical industry includes the manufacture, extraction, processing, purification, and packaging of chemical materials to be used as medications for humans or animals (World Bank Group 1998). Pharmaceutical manufacturing can be separated into two main phases: (a) the production of the active ingredient or drug (primary processing, or manufacture) and (b) the secondary processing, the conversion of the active drugs into products suitable for administration. These two types of pharmaceutical product can either be branded or generic. When the marketing period granted by patent laws and the supplementary protection certificate expire, generics (which are copies of the original products) can be produced and sold, usually at a cheaper price. According to the European Federation

of Pharmaceutical Industries (EFPIA), turning a newly synthesized active substance into a marketable medicinal product takes an average of 12-13 years but only three in ten of these products will produce revenues that more than cover their research and development (R&D) costs (EFIPIA 2010).

The pharmaceutical manufacturing industry produces therapeutic substance (human and veterinary medicines, drugs, and related products) in an increasingly concentrated set of mostly transnational company and sub-contracting facilities. The sector has five broad areas of activity: (a) research and development (R&D), (b) manufacturing, (c) sales and marketing, (d) distribution, and (e) administration.

In 2002, more than half a million people were employed in the pharmaceutical industry in the EU (Vekeman 2005). Medicinal and pharmaceutical products' are important in EU exports with a value of EUR 73.3 billion in 2007, corresponding to 37% of the total exports of chemicals (Gambini 2008). The pharmaceutical industry has been described as a trade in which companies, government regulators and researchers focus on the "safety" of the products and their effects on end users and the environment (Abraham and Davis 2005; Egerstrand, Wester et al. 2009). The continuum however of exposures to pharmaceutical ingredients from development and manufacturing, through marketing and consumption, to waterways, also includes the workplace (Wigmore 2009).

For the manufacturing of pharmaceutical products many facilities have multi product capability and the equipment may in some cases be the same as are operating personnel are. Thus, in the same workplace different raw materials are used, different processes are executed, and different waste streams are generated (Gad 2008). In this highly maintained environment equipment must be cleaned, to avoid cross-contamination. This involves water, steam, detergents, and/or organic solvents. Many steps are automated in these processes, with examples of worker tasks including: (a) weighing and dispensing solids and liquids (using pumps or pouring), (b) charging and discharging solids and liquids from containers and process equipment, (c) manual materials handling, (d) equipment maintenance and repair, and (e) watching controls and processes. The working environments of a manufacturing facility may be noisy, hot, and humid. Surfaces can be hot and slippery. Some surfaces and floors may be covered with dust from the process. Some hazards to employees include moving machinery parts and pressurized pipes and vessels. Some work is done in confined spaces and/or with high-energy sources. In extreme circumstances involving large quantities of highly charged powder particles explosive atmospheres can exist. Solvents can burn and/or explode, especially in organic synthesis. General manufacturing practice and other quality control rules set by regulatory agencies, customers, and/or pharmaceutical organizations cover a number of these processes and the equipment used. Health and safety laws as well as good manufacturing practices and guidelines apply to all of them.

The emphasis of STAMINA project is given on Human Factors (HF), that is, any factor that affects human performance and increases the probability of errors in the workplace. Thus, firstly a review of legislation surrounding the manufacturing process of pharmaceuticals was contacted, so as to reveal if human factors were incorporated in the various laws, directives or guidelines produced by the legislative bodies. Secondly, research at a large Commercial Biopharmaceutical Manufacturing Facility and a small Pharmaceutical manufacturer followed which identified the requirements for the development of Human Factors training program. This paper presents the findings from the first two stages of the project: (a) literature review and (b) research findings. With this part representing the introduction, the rest of the paper is structured with Section 2 presenting the Stamina model, following Section 3 literature review and Section 4 research findings and 5 conclusions and future research agenda.

2 STAMINA MODEL

Under a European funded project a model created to represent the human factors in aviation maintenance was developed. This model was named Safety Training for the Aircraft Maintenance Industry (STAMINA 2010). Under STAMINA, the definition of human factors is "anything that affects an individual's performance of a maintenance task". This is deliberately broad because it needs

to cover the range of factors operating in a particular situation. These factors can be divided into four types: (a) task, (b) individual, (c) team, (d) organization, as seen in Figure 1 below. Also in this model external factors may be considered as pressure from stakeholders.

Figure 1: Levels of human factors.

Much of traditional human factors research has focused on the individual – the interaction of the person with his/her work. Human performance is subject to a range of vulnerabilities and variability's. Thus, taking again the experiences gained from the predecessor project STAMINA in the aircraft maintenance the individual is impacted by the: (a) hardware (the aircraft, tools, equipment, etc), instructional elements (procedures, manuals, regulations, etc,) (b) physical environment (temperature, lighting, etc,) (c) social environment (leadership, communication, aggression, etc) and (d) cultural context (the attitudes, values and norms of the organization, profession or nation)

In all the aforementioned some of the important factors impacting maintenance performance are: Stress, Fatigue, Poor lighting, Extremes of weather, Time or commercial pressure, Distractions, Memory failure and Motivation. From the experience gained in the use of the STAMINA model in the aerospace industry a considerable number of different issues were raised concerning the human factors issues. The ranges of problems were classified into four different levels: the task, the individual, the team and the organisation.

Focussing on the actual task performance errors can be identified together with weaknesses in task design and support.

- Factors affecting the individual include their motivation, attitudes and the demands placed on them by the task,
- Working as a team involved leadership, cooperative work and communication,
- At the wider organizational level are issues of allocation of resources such as personnel and parts, and the game instructions.

The four levels identified correspond to the four STAMINA modules, as seen in Figure 2:

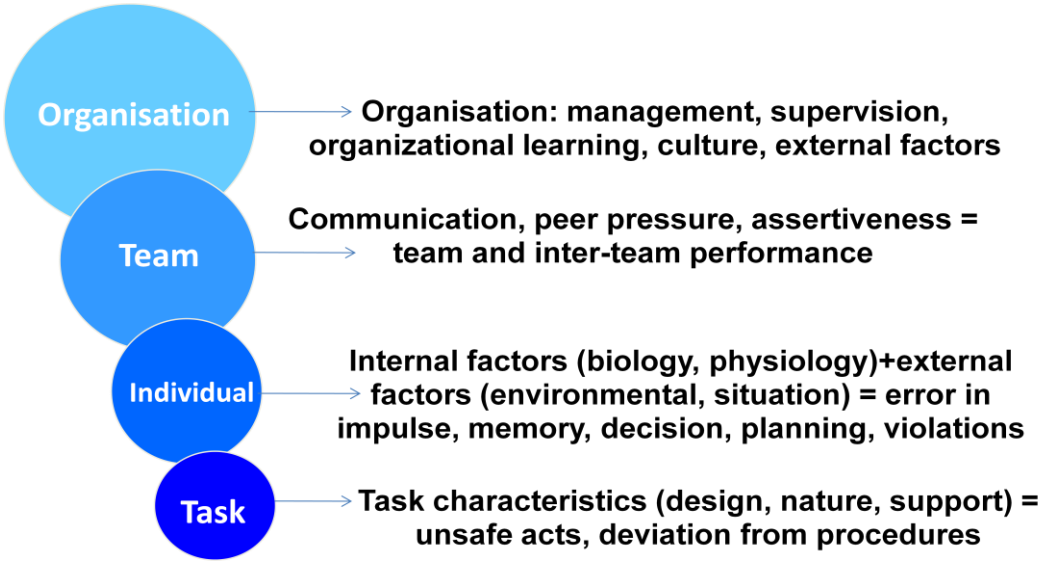

Figure 2. The STAMINA model levels

- The task module focuses on the job of maintaining aircraft – the types of errors that can occur and the task and situational characteristics which can promote or reduce error.
- The individual module focuses on the people doing the maintenance. It identifies the strengths, weaknesses and limitations of humans and how we can work to our strengths and minimise our weaknesses.
- The team module looks at the advantages and disadvantages of working in teams and highlights some ways that we can improve the effectiveness of our teams, in particular through good communications practice.
- The organisational module addresses some of the problems that can limit the effectiveness, safety and reliability of the whole company, such as divergent perceptions of roles and inadequate management of resources.

The STAMINA model proved to offer valuable assistance in the design of a training program for the aviation perspective, thus it was employed again as a main tool to analyze the relevant legislation regarding Biotechnology and Pharmaceutical Manufacturing. In more detail the STAMINA model's levels were used as a filter to separate the relevant legislations, regulations, guidelines and any other relevant form of documentation produced by a public body (European Union, agencies and committees). This separation into the STAMINA levels assisted the analysis and clearly revealed if any human factors were mentioned in the legislation.

3 LITERATURE REVIEW

The literature review and the analysis of the legislation were used to enhance the understanding of the individual working in a Bio/Pharmaceutical Manufacturing (BPM) facility and the surrounding work environment. The review of the relevant legislation focused on two significant groups regarding the Good Manufacturing Practices (GMP) and Occupational Safety and Health (OSH), as its main blocks of literature review (OSHA 2010; World Health Organisation 2010). In the first section (a) the Good Manufacturing Practices, Food and Drug Administration and International Conference on Harmonisation are the main sources used to retrieve the appropriate legislation (FDA 2010; ICH 2010). In the second section (b) the legislation was researched through Occupational Safety and Health, Occupational Safety and Health Administration and European Agency for Safety and Health at Work (EASHW 2010)

3.1 Legislation

Good Manufacturing Practice (GMP)

According to the legislation, as far as the task itself is concerned the organization must produce well documented procedures that describe the job at hand. Furthermore in the vicinity of the worker depending of his specific duties, several documented procedures for handling equipment and/or specific procedures must be in place for guidance. The individual (e.g. worker) has to comply with the hygiene protocols and record his actions in a strict manner. The recording and documentation is extensive as every activity has to be recorded and any deviation reported. The facilities should be kept clean, again following strict protocols and access is restricted, with specific rules applying as far the movement from one area to another in concerned and also to the entry of non-personnel in the production areas. The worker may be required to wear special clothing and in many cases mask and/or protective glasses. His/her obligations include reporting any illness or alteration of his physical health and if it is considered appropriate being removed from his duties.

Levels	Findings
Task	• Procedures (Well documented, Job Descriptions, Manuals, Procedure Recordings) • Repetitiveness (Hygiene protocols, Records Keeping) • Training (Continuous training in all personnel) • Housekeeping (Cleaning and Hygiene protocols) • Work-Tool Conditions (Sufficient and of appropriate quality) • Access (Limited, Restricted)
Individual	• Illness (Reporting, May be Excluded) • Special Clothing and Protection wear • Decision (No decision taken without approval, documentation and recording)
Team	• Team building towards Manufacturing and Quality
Organization	• Culture (Continuous improvement for public health) • Resources & Planning (Quality and Risk management systems) • Training (Continuous training) • Working Conditions (Cleaning and Hygiene protocols) • Work-Tool Conditions (Sufficient and of appropriate quality) • Management & Supervision (Self monitoring, Auditing)

Table 1. Summary of Findings from the literature review (GMP).

As for the ability to make individual decisions relating work ,employees arerestricted to follow protocols and get approval and document any alterations. On the other hand, the Organization must provide resources of high quality based on high standards and plans towards maintaining the public health as its main priority. Also the employer must reinforce the workers with continuous training to establish a coherent understanding of the established procedures e.g. manufacturing, hygiene and quality. Furthermore the regulations show that the organization should establish a self monitoring and auditing (internal audits) system for management and supervision. A more summarized view of the findings in relation to the STAMINA model can be seen in the Table 1.

Occupational Safety and Health (OSH)

From the OSH prospective the aim is to protect the worker from hazards and associated risks and where possible either eliminate or reduce them to an acceptable level. The literature review revealed that the legislation proposes that there should be documented procedures e.g. manuals or recordings, to point towards the hazards of the task and/or the environment. Thus the task should be designed to eliminate hazards and minimize the probability of an error/accident. Also, there should be training programs that assist towards a safer working environment and mechanisms that make all the

appropriate information available to all stakeholders. The workers can assist in the process of identifying potential hazards and they are encouraged to do so.

According to the legislation the individual (e.g. worker) should be part of the various communication mechanisms e.g. feedback. His/her physical conditions and physiological capabilities, as well as age and gender should be incorporated in the planning and design of the work procedures to promote a safe environment. Even special considerations e.g. as monotonous work and fatigue from display monitors should be considered. The training should not only be set, but also recorded, evaluated and if applicable retrained.

Furthermore, the legislation recommends communication among the stakeholders and promotes the individuals participation. Also, through specific practices (e.g. drills and training) the safety mentality should be strengthen. Moreover, as mentioned in the legislation the results of the activities (e.g. training) should be recorded and communicated in all the stakeholder.

The organization should also foster a safety culture, through activities such as clear communication channels and continuous training. According to the legislation, the organization should provide all the appropriate resources, policies and establish procedures to minimize the hazards from the working environment. Through well defined supervision e.g. monitoring and auditing, the organization should observe and evaluate the plans laid towards safety and communicate the findings. A more summarized view of the findings in relation to the STAMINA model can be seen in the Table 2.

Levels	Findings
Task	• Procedures (Well documented, manuals, procedure Recordings), • Design (Planning, reviewing and revising), • Pressure (Keeping vigilant focus of current and future potential hazards), • Training (Training and information available), • Housekeeping (Prevents carcinogens and other hazardous), • Work-Tool Conditions (Sufficient and foresees for new technologies), • Access (Limited but information available).
Individual	• Communication (Well established procedures and feedback), • Physical conditions (human behavior, physical / physiological capabilities), • Illness (Prevent harmful agents e.g carcinogens, consideration of working style and health, taking breaks from display screens), • Competence (Train, evaluate and retrain), • Biological conditions (Posture, position, gender and older and disabled), • Special Clothing and Protection wear, • Error in impulse (monotonous work to be alleviated).
Team	• Pressure (Record and communicate the results), • Communication (Among stakeholders), • Organisational factors (Participation and consultation), • Practices (Teamworking e.g. safety drills, training, social relationships, participation).
Organization	• Culture, • Communication, • Resources & Planning (policies, documentation,, controls and procedures), • Training (Continuous training, evaluated, recorded), • Working Conditions (Special considerations e.g change rooms, prevention, planning), • Management & Supervision (Well defined, Monitoring, Auditing), • Learning organization (Monitoring, procedures, observations and evaluations).

Table 2. Summary of Findings from the literature review (OSH).

The process of identifying the human factors in relevant legislation is a complicated and complex process. Firstly, the amount of the legislation contributes towards the complexity and secondly the

different forms of legislation e.g. regulations, directives, guidelines etc make the reviewing more complicated. Although, these findings consist of only the reviewed legislation they portray a clear view of the pharmaceutical manufacturing industry. In some cases the findings overlap each other since the human factor elements of the STAMINA model is designed to aid a relative new research field and hence its value and development grow with each application.

Furthermore, in an attempt to investigate potential issues of concern that can provide further assistance to the development of the STAMINA model and therefore the applicability of human factors in the relevant legislation a theoretical inspection of the findings were conducted.

3.2 Analysis

Good Manufacturing Practice (GMP)

The findings presented in section 3.1 describe a worker in an environment ruled by documented procedures assisting him on his duties. Furthermore among the workers instructions is to document all the relevant actions taken and report any deviations. Many times due to the special conditions this worker has to fulfill his duties in a constricted environment wearing special protective garments and mask/glasses. On the other hand the organization must produce and make available all the documents and instruct the worker accordingly, having always as a top priority the elimination of contamination of the product. Also, the organization has to conduct self monitoring and auditing on a regular occurrence.

Although, all these are necessary and mandatory so as to protect the product e.g. drug and hence the public health, there are human factors that can be considered. For example, the workers need to interact as to form social networks, interactions and teams that can facilitate group identification and lead to more smooth coordination and collective action. In parallel the parameter of auditing/inspecting can be an issue among the workers and again prohibit the teamwork. Internal audit staff not possessing prior experience in auditing, may not understand the wide range of existing and potential problems nor possess problem-solving skills (Hutchinson and Zain 2009). In many organizations, a major cultural shift is required to change employee attitudes and behaviour so that they willingly and consistently share their knowledge and insights and thus help management and control process. A graphical representation of the mentioned example can be seen in Figure 3.

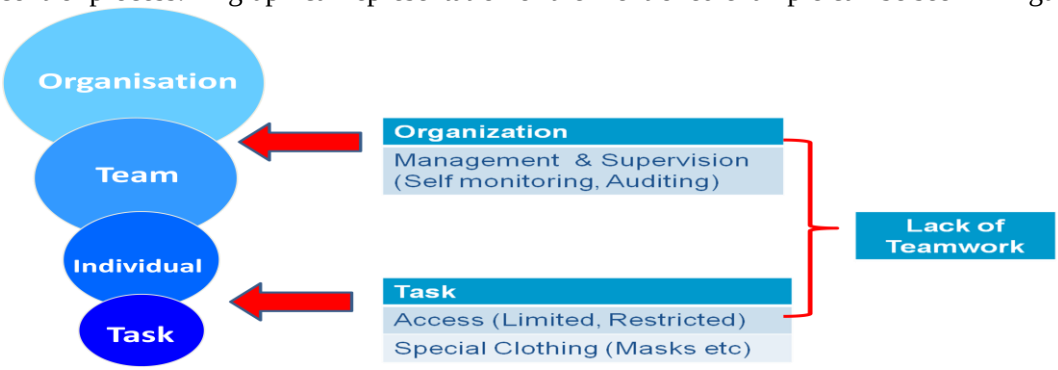

Figure 3. Example GMP Human Factors

Occupational Safety and Health (OSH)

The findings presented in section 3.1 revealed, that the legislation requires that the task should be designed with limited hazards as far as is reasonably practicable. Also, there should be training programs that assist towards a safer working environment to all stakeholders. Evermore, there should be various communication mechanisms and special attention given to physical, physiological and biological factors. Human factors also take into account special considerations for example monotonous work and team working. As reported under the aforementioned regulations monitoring and auditing exist, but attention is given to the organization's responsibility to evaluate, plan and

communicate the processes. Thus, making the auditing processes more effective with fewer reactions from the audited parties.

Although, all these findings are necessary and highly recommended so as to promote a safe working environment, there are human factor interactions that need to be considered. The OSH group of legislations, regulations, standards and guidelines, appear more focused on human factors than GMP, but there are some issues of concern like the pressure it inflicts. Pressure that is produced from the involvement of the individual to recognize, evaluate and respond to the identification of potential hazards in his working environment. This pressure, as seen in Figure 4, is built in between all levels of the STAMINA model. In more detail, between the task and individual the pressure is produced as the worker has to pay attention for current and future potential hazards, leaving room to interpretation (of his abilities) if his/her identification is not preventive and/or adequate. Also, between the individual and the team, as the individual must be trained and retrained in a case that his/her training failed to be of the desired level or where regulation specifies annual/biannual refresher training (for example Confined Space Entry). Moreover the pressure exists between the team and the organization as the latter creates processes e.g. drills, that have to be recorded and the results positive or negative communicated to all stakeholders. The pressure produced can expose the workers to stressful work conditions that could potentially increase risk of psychosocial issues including anxiety and depression.

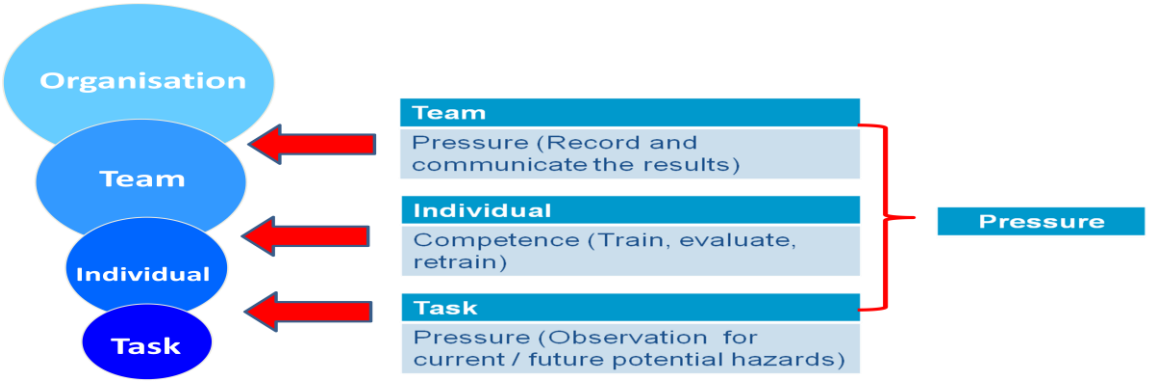

Figure 4. Example OSH Human Factors.

3.3 Overall

It can be stated that, the compliance with the legislation regarding the GMP regulations are the main requirement for pharmaceutical production, but as reported in the previous section does not directly emphasize the human factors aspect. On the other hand, the researched OSH legislation gives more attention to human factors (although indirectly) and could be used as guidance towards effective organizational planning that incorporates more of these aspects. Furthermore, as mentioned the future trends in pharmaceutical manufacturing and in industry as a whole, reinforces the need of a stronger utilization of human factors aspects, as many issues of concern can be avoided or their effect minimized.

As an overall conclusion, if an organization uses both GMP and OSH legislation to their full effect it will provide the foundations for a safe, dynamic working environment that has as a main priority the production of safe pharmaceutical products of high quality, but also respect the individual needs and abilities of the worker. Thus, reducing the likelihood for errors produced from human factors or at least will have a clear view of their existence and minimize their effect on manufacturing.

However, it is the use of models like the STAMINA model that can assist the design and utilization of human factors, either in the prospective of creating legislation or designing a management/manufacturing plan for the industry. The STAMINA model, through the process of the literature review proved to be a valuable tool, within which the human factors in pharmaceutical manufacturing legislation were indentified and analyzed.

Even thought this research identified possible human factor related issues in the legislation, it does not assume that pharmaceutical production organizations does not consider human factors in their practices. Thus, the next step was to gather data from the industry itself.

4 RESEARCH

4.1 Research methods and tools

The data gathering was conducted in parallel at a large Commercial Biopharmaceutical Manufacturing Facility and a small Pharmaceutical Manufacturing Facility in different European countries.

The methods used to gather the data was by: (a) walk-arounds, (b) interviews and (c) survey. The methods were employed as to have a full strong view of the researched field, as seen in Table 3. In more detail, the purpose of walk-arounds was to gain a first-hand perspective of the facility activities and the context (conditions) within which they are carried out. During the observations, the researchers looked for and noted issues of relevance to Human Factors as characteristics of the processes and activities observed. Whereas, the objective of the interviews was to gain employees perspective on the operations carried out at each facility. Interviews lasted up to one hour, were carried out in an informal fashion, and interviewees were various questions. The objective of the survey was to enable a larger-scale assessment of Human Factors issues specific to each of the two facilities. The Survey was made available to employees at all levels and all departments. Participants were invited to voluntarily submit their perceptions, opinions, and comments in writing, provided yet another source of information regarding factors that influence human performance and endanger worker safety, reliability, and pose a risk to the product.

Data gathering tools and methods		
Walk-arounds	**Interviews**	**Survey**
• Cognitive demands they pose on the human operator (e.g., memory, attention, decision making, calculations, manual skills), • Physical demands they pose on the human operator (e.g., dexterity, posture), • Verbal communication requirements, immediate or deferred, between persons in the same or different locations • Non-verbal communication requirements (e.g., paperwork), • Interaction with automation and equipment/tools required for the process, • Potential human errors, • Potential machine errors, • Potential human-machine interaction errors, • General workload issues.	• Duties and responsibilities, • Perception of what are the most vulnerable activities within their department and/or the entire Facility, • Perception about human error, • Company's approach to errors (reporting, addressing errors), • Inspections, self-audits • staff (qualifications, adequacy, motivation levels), • Pressures and constraints, and their sources, • Work hours, • Methods for addressing reports/deficiencies.	• Perceptions, • Opinions, • Comments.

Table 3. Summary of the Data gathering tools and methods used

4.2 Research Findings

The outcome from the observations and interviews were classified using the STAMINA model categories and sub-categories within each. In this manner, it was possible to arrive at a comprehensive

list of Human Factors issues that have the potential to influence human performance and lead to errors/events in BPM. An overall look at the findings from the two facilities studied show that the HF issues are largely common. A summary of the research findings be seen below. These are categorized as (a) skills/competencies required, (b) survey, (c) perception about human factors.

Skills/Competencies required (factors that can lead to errors/events in BPM)

Levels	Findings
Task	• Preserving attention to detail, • Set up and Clean processes (special characteristics, risks), • Responding to time/operational/production pressures, • Adequate understanding of process, • Optimal teaching/learning of procedures, • Dealing with interruptions, • Validation of new processes, • Situational/ risk awareness/appreciation, e.g., risk to product, to customer, to company, • Interpreting rules and procedures and guidance, • Need for good technical and social competence, • Coordination required across dispersed functions and work areas.
Individual	• Physical, cognitive capabilities and limitations on job performance (dealing with fatigue, interruptions, distractions, complacency, etc.), • Identifying the preconditions / precursors for errors, • Patience: resistance to rushing; maintaining vigilance, • Risk assessment (formal/informal), • Professionalism: sense of ownership in task/process/product-outcome, • Importance of values, attitudes and motivation in job performance, • Relationship between pressure and stress, and its impact on human performance and health, • Combating complacency, • Assertiveness: HF/social competence, • Adherence to SOPs (reason, importance, addressing non-adherence).
Team	• Teamwork (benefits, challenges), • Danger of diffusion of responsibility, • Communication (effective, frequent, different types of, as a function of level, of time of day, limitations of), • Transfer of responsibility, • Hand-over/shift changes: ensuring situation awareness/common operational picture Quality support needed on shifts, transfer of responsibility, planning activities near hand-over,
Organization	• Management of unscheduled-tasks, • Monitoring (without losing focus), • Cross training (advantages, disadvantages), • Leadership (planning, prioritizing, • Risk assessment (formal/informal), • Introduction of new technologies/equipment, • Culture (company/organizational/safety), • Time-management, • Workload-management, • Planning, prioritization, • Establishing proper procedures Reporting (importance, value, process = what, how, when).

Table 4. Summary of Skills/Competencies required

Survey
Consolidation of the findings from the surveys revealed the HF issues that may lead to errors and ways to handle. Specifically, insofar the **Task factors** are concerned, the primary HF-related issues that employees generally agree are potentially error-inducing and threaten safety are: (a) Time Pressure, (b) Distractions, and (c) Interruptions. Furthermore "Unclear procedures" was an issue that appeared to specifically concern employees– perhaps due to the much larger range of activities which require detailed procedures at that facility vs. the other. There was a general trend for employees to believe that the HF issues ranking high on their list of concerns are also those for which they are not well-equipped (through formal or informal training) to effectively address.

Regarding the **Individual factors**, the same issues again seemed to concern employees were: "Stress," "Fatigue," and "Personal problems". Some employees agreed they had some type of training on how to handle fatigue. All respondents appear to believe that "Stress" is an issue for which they require more assistance in dealing with. Respondents from the larger facility placed emphasis on the issue of "Lack of motivation" and "Personal problems."

Both **Team and Organizational factors** appeared to generate more consensus regarding their potential to induce errors. At least 1/2 of the listed Team and Organizational issues generated agreement that they are potentially error-inducing, compared to only 1/3 of the listed Task and Individual issues. Within Team factors, specifically, the issue that appeared to concern all respondents, regardless of target group and facility, the most was the unclear roles and responsibilities. Another issue identified was a general unwillingness to ask for help from team member/colleague.

The top- issue f from all target groups and facilities indicated not having been taught/shown how to deal with concerned Effective Communication (Lack of communication among team members and Lack of effective way for conveying ideas). Lastly, within Organizational factors, respondents from different facilities responded differently about issues that may lead to errors. (a) at the smaller facility respondents selected, (b) Lack of effective response from Supervisors/Management regarding reported safety issues, (c) while respondents from the larger facility selected, (d) Insufficient workforce, (e) Inadequate tools and equipment, (f) Poor documentation as issues which may lead to error. In terms of knowing ways to handle issues, the interesting finding has to do with the larger facility response, which highlights the need for training regarding a clear leadership structure.

Perceptions about HF issues

- The role of official documentation is primarily to ensure signing-off of work completed,
- It is up to me to ensure the quality of my work (even if my colleague/Supervisor verifies or counter-signs my work),
- It is important to debrief and critique actions and decisions, after a job.

5 CONCLUSIONS AND FUTURE RESEARCH

It is found from the literature review and analysed that an organization applying both GMP and OSH legislation will provide the foundations for a safe, dynamic working environment that has as a main priority the production of safe pharmaceutical products of high quality, but also respect the individual needs and abilities of the worker. Thus, reducing the likelihood for errors produced from human related sources or at least will have a clear view of their existence and minimize their effect on manufacturing.

However, it is the use of models like the STAMINA model that can assist the design and utilization of human factors, either in the prospective of: (a) creating legislation, (b) classifying research finding and analysing them respectively and (c) designing a management/manufacturing plan for the industry. The STAMINA model, through the process of the literature review and research proved to be a valuable tool, with which the human factors in pharmaceutical manufacturing were indentified and analyzed.

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